

IN THE CLAIMS:

Kindly amend Claims 1, 2, 7-14 under the provisions of 37 CFR §1.121(a) as follows:

R1 *Sub C1*

1. (Amended) A pharmaceutical composition containing as active principles Vitamin D and a calcium salt which comprises a binding agent selected from the group consisting of propylene glycol, a polyethylene glycol of molecular weight between 300 and 1500, liquid paraffin and silicone oil, said Vitamin D being present in an amount of 500-1000 I.U. of Vitamin D and said calcium salt being present in a ratio of 1-2 g of calcium, calculated as elemental calcium, for each 500-1000 I.U. of Vitamin D.

2. (Amended) A pharmaceutical composition according to Claim 1, in which the calcium used is in the form of a salt selected from the group consisting of phosphate, glycerophosphate, carbonate, bicarbonate, lactate, citrate, tartrate, gluconate and chloride.

7. (Amended) A pharmaceutical composition in a sachet dosage form according to Claim 1, containing the propylene glycol in a quantity comprised between 5-15% by weight calculated on the total composition.

R2

8. (Amended) A pharmaceutical tablet according to Claim 1, containing liquid paraffin or silicone oil.

9. (Amended) A pharmaceutical composition in a sachet dosage form characterized as follows:

Tribasic calcium phosphate	3.100 g
(corresponding to 1200 mg of Ca^{++})	
Cholecalciferol (Vit. D_3) 100,000 IU/g	0.008 g
(corresponding to 800 IU)	
Propylene glycol	0.800 g

Sunset Yellow	0.002 g
Colloidal silica	0.120 g
Lemon flavoring	0.100 g
Microcrystalline cellulose- MCC	0.200 g
Sodium saccharin	0.015 g
Anhydrous citric acid	0.165 g
Sucrose monopalmitate	0.120 g
Mannitol q.s. to	7.000 g

10. (Amended) A pharmaceutical composition in a sachet dosage form characterized as follows:

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Tribasic calcium phosphate (corresponding to 1200 mg of Ca^{++})	3.100 g
Cholecalciferol (Vit. D ₃) 100,000 IU/g (corresponding to 800 IU)	0.008 g
Polyethylene glycol	0.800 g
Sunset Yellow	0.002 g
Colloidal silica	0.120 g
Lemon flavoring	0.100 g
Microcrystalline cellulose- MCC	0.200 g
Sodium saccharin	0.015 g
Anhydrous citric acid	0.165 g
Sucrose monopalmitate	0.120 g
Mannitol q.s. to	7.000 g

11. (Amended) A pharmaceutical composition in a tablet dosage form characterized as follows:

Tribasic calcium phosphate (corresponding to 1200 mg of Ca^{++})	3.100 g
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Cholecalciferol (Vit. D ₃) 100,000 IU/g (corresponding to 800 IU)	0.008 g
Liquid paraffin	0.500 g
Sodium carboxymethyl cellulose	0.050 g
Sodium saccharin	0.015 g
Orange flavoring	0.100 g
Sorbitol q.s. to	4.400 g

12. (Amended) A pharmaceutical composition in a tablet dosage form characterized as follows:

Tribasic calcium phosphate (corresponding to 1200 mg of Ca ⁺⁺)	3.100 g
Cholecalciferol (Vit. D ₃) 100,000 IU/g (corresponding to 800 IU)	0.008 g
Silicone oil	0.500 g
Sodium carboxymethyl cellulose	0.050 g
Sodium saccharin	0.015 g
Orange flavoring	0.100 g
Sorbitol q.s. to	4.400 g

13. (Amended twice) A process for the preparation of a pharmaceutical composition according to Claim 1, characterized by the following steps:

- In a granulator turning at high speed, distributing a binding agent, consisting of propylene glycol or low molecular-weight polyethylene glycols over a calcium salt;
- Adding colloidal silica, approximately 25% of mannite, citric acid, and sodium saccharin, and mixing for an appropriate time and at an appropriate speed to produce a first mixture;
- Adding a second mixture, prepared separately, consisting of sucrose palmitate, a suspending agent, flavoring, a coloring agent, approximately 75% of the mannite and the Vitamin D₃, and mixing together with the first mixture to form a granulate; and

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d) Distributing the granulate thus obtained into sachets.

14. (Amended twice) A process for the preparation of a pharmaceutical composition according to Claim 1, characterized by the following steps:

- a) In a granulator turning at high speed, placing a binding agent, consisting of liquid paraffin or silicon oil, over a calcium salt;
- b) Adding in order, to a mixture of colloidal silica, carboxymethyl cellulose and sodium saccharin previously sifted, the Vitamin D₃ and sorbitol, mixing thoroughly every time before a new ingredient is added, and pouring the mixture into the rotating granulator and mixing for an appropriate time and at an appropriate speed to form a granulate; and
- c) Compressing the granulate to a required weight to obtain tablets.
